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| EXAMINER | | | | |
| EASTWOOD, DAVID C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,500

Applicant(s)

ZHOU ET AL.

Examiner

DAVID EASTWOOD

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 1/12/2009. Claims 1-20 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 recites the limitation "open string" in Page 3 line 1. There is insufficient antecedent basis for this limitation in the claim.
3. Claim 5 recites the limitation "open string" in page 3 line3-4. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 6 recites the limitation "retrieval noose" in page 3 lines 6-7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7-8, 15 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Specter (US 5135222).

Regarding Claims 1, 7-8, 15, and 19, Specter discloses an easily retrieved biological specimen pouch comprising a flexible wall (10a), an open end and a closed end (Figure 1, top and bottom of bag), and said specimen pouch can receive the biological specimen therein; said flexible wall of the open end of the specimen pouch has discontinuous serration (N); on said serration, there are slots (12,13) through which string can pass, wherein the string opens and closes the specimen pouch (Figure 1), wherein the pouch deployment and retrieval string opens and closes the specimen retrieval pouch (Column 4 lines 51-60), said flexible wall of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by synthetic fiber (Column 4 lines 18-21)

7. Claims 1, 4-13, 15 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Colon et al (US 6409733).

Regarding Claim 1, 4-13, 15 and 19, Conlon et al discloses an easily retrieved biological specimen pouch comprising a flexible wall (79), an open end (76) and a closed end (77), and said specimen pouch can receive the biological specimen therein; said flexible wall of the open end of the specimen pouch has discontinuous serration (85,86); on said serration, there are slots (85,86) through which a string can pass, wherein the string opens and closes the specimen pouch (Figure 8), wherein said open spring (47) is made of any materials which can save the changed shape and return to

the original or near the original shape when disentangled, wherein said open spring (47) is made of the following materials: shape memory alloy wires, shape memory alloy pieces and alloy spring steel (Column 4 lines 45-50), wherein said retrieval noose (97) is made of the wires of macromolecule materials, compound materials or metal materials, wherein said flexible wall (79) of the specimen pouch is made of the soft macromolecule materials or compound materials, wherein said flexible wall (79) of the specimen, pouch is made of the soft macromolecule materials or compound materials which are enhanced by metal net or synthetic fiber, wherein said flexible wall (79) of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by memory alloy fiber net or synthetic fiber net, wherein said soft macromolecule materials are selected from the following elastomer or polymer materials: Silicon Rubber, Polyurethane, Polyethylene, Polypropylene, Silicone, Ethenoid Resin and Polytetrafluoroethylene (Column 6 lines 15-24), wherein said string (95) is Connected to a distant end of an inner sheath (26), and the specimen pouch (75) is installed in front of the distant end of the inner sheath and inside a distant end of an outer sheath (Figures 1 and 2), wherein one end of the said string (95) is connected with a slipknot or slip block (97), a noose structure is formed when the other end passes through the slots (85,86) in the serration of the open end in the specimen pouch and then the slipknot or slip block (97), wherein said the relative position of the outer sheath (25) and inner sheath (26) is fixed by the orientation button (56).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2-3, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Avellanet (US 6278057) further in view of Cope et al (US 5064428).

Regarding Claims 2-3 and 16-17 and 20, Specter discloses the claimed invention except for said string is made of any materials which can save the changed shape and return to the original or near the original shape when disentangled, said string is made of the following materials: shape memory alloy wires or pieces or alloy spring steel, wherein the pouch deployment and retrieval string returns to an open state based on temperature of a body.

However, Avellanet discloses nickel titanium alloy (nitinol) wires/strings for use with snares and surgical baskets (Column 4 example 1 and column 5 example 2) and are naturally trained to form a desired size in vivo (Column 5 lines 50-52), Cope et al teaches that nitinol is transformable from a deformed state to a predetermined trained shape once heated to its operable range (Column 2 lines 47-65). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the nitinol string as taught by Avellanet. Doing so would provide a support structure for the entire circumference of the opening of the bag once deployed in vivo.

Regarding Claim 18, the invention of Specter as modified by Avellanet discloses the claimed invention except for wherein the temperature is in the range of 15°C-33°C.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to set the shape memory alloy transformation temperature to the range of 15-33°C, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claims 4-6, 9-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Conlon et al (US 6409733).

Regarding claim 4-5, Specter discloses the claimed invention except for said open spring is made of any materials which can save the changed shape and return to the original or near the original shape when disentangled, wherein said open spring is

made of the following materials: shape memory alloy wires, shape memory alloy pieces and alloy spring steel.

However, Conlon discloses an open spring (47) which is made of a shape memory alloy (Column 4 lines 45-50). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the open spring as taught by Conlon. Doing so would provide a secondary support structure for deploying the specimen bag in vivo.

Regarding claim 6, the invention of Specter as modified by Conlon discloses the claimed invention except for said retrieval noose (96 Conlon) is made of the wires of macromolecule materials, compound materials or metal materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the retrieval noose of macromolecule materials, compound materials or metal materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claim 9-10, Specter discloses the claimed invention except for said flexible wall of the specimen pouch is made of the soft macromolecule materials or compound materials which are enhanced by memory alloy fiber net or synthetic fiber net, said soft macromolecule materials are selected from the following elastomer or polymer materials: Silicon Rubber, Polyurethane, Polyethylene, Polypropylene, Silicone, Ethenoid Resin and Polytetrafluoroethylene.

However, Conlon discloses a multi layered flexible wall basket made of Polyurethane enhanced by a Kevlar mesh/net (Column 6 lines 15-23). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the flexible walled basket with reinforcing net/mesh as taught by Conlon. Doing so would provide a retrieval bag with increased tensile strength along its annular walls.

Regarding Claim 11-13, Specter discloses the claimed invention except for said string is connected to a distant end of an inner sheath, and the specimen pouch is installed in front of the distant end of the inner sheath and inside a distant end of an outer sheath, wherein one end of the said string is connected with a slipknot or slip block, a noose structure is formed when the other end passes through the slots in the serration of the open end in the specimen pouch and then the slipknot or slip block, said the relative position of the outer sheath and inner sheath is fixed by the orientation button.

However Conlon discloses a string (95) connected to a distant end of an inner sheath (26) where a specimen pouch (77) is in front of the distal end of an inner sheath inside a distal end of an outer sheath (25) where the string forms a slipknot (97) forming a noose structure (Figure 2 and 9) and the position of the inner sheath relative to the outer sheath is fixed by an orientation button(56) (figure 3 and 5) (Column 9 lines 4-7). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the deploying apparatus as taught by Conlon. Doing so would provide a device for deploying the specimen bag in vivo.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Specter (US 5135222) in view of Matey et al (US 5649021).

Regarding Claim 14, Specter discloses the claimed invention except for said open end of the specimen pouch is colored distinctly from the biological specimen observed under the endoscopic equipment.

However, Matey discloses a laparoscopic tool used in vivo having a unique color marker not found on the interior of the abdomen (Column 3 lines 55-59). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Specter with the contrasting color as taught by Matey. Doing so would provide a specimen bag which would be easily identifiable with known endoscopic devices in vivo.

Response to Arguments

13. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See references cited page form 892.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/30/09